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October 25, 2011

VIA ELECTRONIC MAIL

Dr. Layla Issa Batarseh
Middle East and North Africa Office/
Senior Regional Advisor
Office of International Programs
U.S. Food & Drug Administration
While Oak Building, Room 3418-A
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Re: *Donor Suitability/Eligibility Recommendations*

Dear Dr. Batarseh:

As you know from our September 23, 2011 letter and subsequent conversation, we are representing Saudi Arabia's Food and Drug Authority (SFDA) in proceedings before the FDA regarding the agency's consideration of modifications to current blood and blood component donor suitability/eligibility recommendations.

We very much appreciate the gracious response we received to our September 23 letter – including the FDA's agreement to adjourn the September 26, 2011 meeting. As we stated in our letter, we do not wish unduly to delay the FDA's consideration of this issue. We note, however, that we have not received any additional information from the FDA in response to the detailed requests we made in our letter. Our failure to obtain responsive information is impeding our ability to provide the FDA with a detailed factual and scientific submission addressing the recommendations of the Transmissible Spongiform Encephalopathies Advisory Committee ("TSE Advisory Committee") to defer or find ineligible certain blood donors based upon their having lived in Saudi Arabia during the 1980 to 1996 time period. We remain concerned that, without access to the information that has been requested, it will be difficult adequately to address whether the TSE Advisory Committee has taken cautionary principles too far in making these recommendations. In particular, the SFDA still needs information about the three vCJD

cases on which the TSE Advisory Committee's recommendations rest. The SFDA continues to view this information (the request for which pre-dates our September 23, 2011 letter) as critical to its being able to respond to the TSE Advisory Committee's recommendations.

We also note that, while one of the items we requested in our September 23, 2011 letter (the transcript of the August 1, 2011 meeting) was recently posted on the FDA's website, its public availability (as well as that of the webcast of the meeting) concerns us given that the available public record on this issue does not adequately reflect the SFDA's position. While SFDA representatives made a short, telephonic presentation at the August 1, 2011 meeting, the scheduling of the meeting during Ramadan made it impossible for these representatives to attend in person or to present a more detailed response. Thus, the current public record remains unbalanced and fraught with what we believe are faulty and incomplete factual and scientific data.

In a September 24, 2011 email to us, you explained that you would not be able to respond to us until the FDA had an opportunity to engage in internal discussions regarding our letter. We fully understand (and are respectful of) that position. However, we were hopeful that by this time – over four weeks after receiving our letter – the appropriate FDA officials would be in a position to discuss our requests and to begin to advance the flow of responsive information to our client. We certainly do not mean to push the FDA to meet before it is ready, but we do want to be sure that the time that has gone by without a response in no way prejudices our client's ability to respond fully on this issue before the FDA makes a determination whether to accept or reject the TSE Advisory Committee's recommendations. In addition, while we and our client are committed to addressing this issue as soon as practicable after obtaining the requested information, we will need time to review any information provided by the FDA.

We also wanted to advise you that, while waiting for the critical information requested in our September 23, 2011 letter, we have not sat idle. We and our client have continued to seek information from other sources – including from other governments. In that regard, we note that several of our attorneys will be traveling to Saudi Arabia to obtain relevant information after the Hajj season concludes in mid-November and that we also intend to visit (as necessary) other sites where we believe relevant information will be available – including Edinburgh and Canada. While we will need time to complete these visits, we believe that they will prove to be very helpful in developing a comprehensive submission to the FDA.

In seeking information from other sources, we principally are gathering epidemiologic and other data relevant to the TSE Advisory Committee's recommendations that we believe will be helpful to both the SFDA and the FDA in reaching a reasoned decision regarding this issue – including data on the following issues:

- We intend to explore more fully how country attribution of the three vCJD cases has been made by the TSE Advisory Committee. It appears that the Committee is taking a different approach in attributing cases to countries than is being taken by the World Health Organization – leaving the impression that there is an effort to have two North American cases (one US and one Canadian) attributed to Saudi Arabia, to the detriment of Saudi Arabia. In addition, some of the analysis presented by the TSE Advisory Committee appears to be inconsistent with the approach used by the FDA in prior cases. We would like to understand the justification for this apparent deviation.

- We also intend fully to develop the steps taken by Saudi Arabia to ban imports of UK beef starting in 1990. We do not believe that the TSE Advisory Committee gave credence to this comprehensive ban in making its recommendations.

- The Committee attached significant weight to British-derived export data for the period of 1980 to 1996. The SFDA finds this to be surprising given that Dr. Robert Will acknowledged to Saudi representatives that the data are based on soft statistics. In addition, while more than eighty countries imported UK bovine, only a selected few were cited in the TSE Advisory Committee's presentation at the August 1, 2011 meeting – suggesting that the data were cherry-picked. We intend to pursue this subject -- and will continue to view the data presented by the TSE Advisory Committee as suspect unless the data can be verified by Saudi authorities.

- Although North America has a very significant population of UK expats – a substantial majority of which have been exposed to transmissible BSE before emigrating to North America – only two vCJD cases have been cited. In contrast, Saudi Arabia, a country with a relative handful of expats resident in North America, no known transmissible BSE and a population with a well-known dietary preference for lamb and goat, is cited with three cases. We intend to develop data that we believe will show, among other things, that there has been no exposure to vCJD from domestic sources in Saudi Arabia. We also intend to review the dietary preference issue more fully – including whether UK beef imported to Saudi Arabia was sold nationally or whether it was principally sent to grocery stores frequented by non-Saudis.

We would, of course, welcome any information you might have on any of these issues.

We remain ready to meet with you or with any of your colleagues who are interested in this topic (at whatever level of the FDA they sit) to discuss our information requests. In the

meantime, please do not hesitate to call if there is any information you need from us to advance this process.

Sincerely,

Ralph C. Ferrara
Ann M. Ashton

CC: Dr. Ginette Y. Michaud
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